Notice of Allowability	Application No.	Applicant(s)
	09/585,817	SCHENK, DALE B.
	Examiner	Art Unit
	Christopher J Nichols, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *19 May 2004*.

2. ☒ The allowed claim(s) is/are *11,15,16,19,21-25 and 58*.

3. ☒ The drawings filed on *14 November 2003* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 5.19.04 / 5.11.01
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 19 May 2004 has been received and entered in full.

2. The Examiner notes that Applicant did not file a Appeal Brief on 14 November 2003 but an "AMENDMENT/ARGUMENT AFTER NOTICE OF APPEAL". The Office was mistaken to take the arguments as an Appeal Brief. However, the fact remains that the Amendment and Arguments filed on 14 November 2003 were received and entered in full. Further, the Examiner *withdrew* finality to address said amendments and arguments, thus the last Office Action was a Non-Final Rejection (21 January 2004).

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. All Rejections and Objections in the previous Office Action (21 January 2004) are hereby *withdrawn* and/or *moot* in view of the instant Examiner's Amendment.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the Title:

ACTIVE IMMUNIZATION OF ASCR FOR PRION DISORDERS

In the Claims:

Claims 1-10 (Cancelled)

Claim 11 (Currently Amended) A method of treating a prion disorder associated with AScr in a mammalian subject suffering from the disorder, comprising administering to the subject a dosage of an agent effective to produce an immune response comprising antibodies against the agent ~~an amyloid component derived from a prion precursor protein (PrP) including genetic variants of the PrP associated with hereditary amyloidosis~~ and an adjuvant that augments the immune response to the agent ~~the amyloid component~~, and thereby treating the disorder, wherein the agent is PrP ~~including genetic variants of the PrP associated with hereditary amyloidosis~~ or AScr.

Claims 12-14 (Cancelled)

Claim 15 (Currently Amended) The method of claim 11, wherein the agent ~~said amyloid component~~ is AScr.

Claim 16 (Previously Presented) The method of claim 11, wherein said agent is PrP.

Claims 17-18 (Cancelled)

Claim 19 (Previously Presented) The method of claim 11, wherein said agent is a peptide linked to a carrier molecule.

Claim 20 (Cancelled)

Claim 21 (Previously Presented) The method of claim 11, wherein said adjuvant is selected from the group consisting of QS21, monophosphoryl lipid, and alum.

Claim 22 (Currently Amended) The method of claim 11, wherein said immune response is characterized by a serum titer of the antibodies of at least 1:1000 with respect to the agent ~~amyloid component~~.

Claim 23 (Currently Amended) The method of claim 22, wherein said serum titer of the antibodies is at least 1:5000 with respect to the agent ~~amyloid component~~.

Claim 24 (Currently Amended) The method of claim 11, wherein said immune response is characterized by a serum titer of the antibodies against the agent ~~amyloid component~~ corresponding to greater than about four times higher than a serum titer of antibodies measured in a pre-treatment control serum sample.

Claim 25 (Previously Presented) The method of claim 24, wherein said serum titer of the antibodies is measured at a serum dilution of about 1:100.

Claims 26-57 (Cancelled)

Claim 58 (New) The method of claim 16, wherein the agent is selected from the following PrP genetic variants: Leu102, Val167, Asn178, and Lys200.

6. Authorization for this examiner's amendment was given in a telephone interview with Rosemaire Celli on 22 September 2004.

Summary

7. Claims **11, 15, 16, 19, 21-25,** and **58** are hereby allowed.

8. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
September 23, 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER